FORM-PTO-1390 (Rev. 9-2001) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: 027650-975

U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5): Unassigned 10/070926

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/SE00/01782	14 September 2000 (14.09.2000)	17 September 1999 (17.09.1999)

TITLE OF INVENTION
A SYSTEM FOR MONITORING AND CONTROL IN THE STERILISATION OF AN OBJECT

APPLICANT(S) FOR DO/EO/US
MÖLLER, Håkan; NÄSLUND, Lars; KRISTIANSSON, Anders

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☒ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is attached hereto.
   b. ☒ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
14. ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information:

Publ. Appln. No. WO 01/19687; Two (2) sheets of drawings; PCT Forms IPEA/401 and ISA/210.

21839

10/070926 JC10 Rec'd PCT/PTO 13 MAR 2002

U.S. APPLICATION NO (If known, see 37 C.F.R. 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
Unassigned	PCT/SE00/01782	027650-975

21. ☒ The following fees are submitted:	CALCULATIONS	PTO USE ONLY
Basic National Fee (37 CFR 1.492(a)(1)-(5)):		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO $1,040.00 (960)		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO $890.00 (970)		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO $740.00 (958)		
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) $710.00 (956)		
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) $100.00 (962)		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 1,040.00	
Surcharge of **$130.00 (154)** for furnishing the oath or declaration later than 20 ☐ 30 ☐ months from the earliest claimed priority date (37 CFR 1.492(e)).	$	

Claims	Number Filed	Number Extra	Rate		
Total Claims	8 -20 =		X$18.00 (966)	$	
Independent Claims	1 -3 =		X$84.00 (964)	$	
Multiple dependent claim(s) (if applicable)			+$280.00 (968)	$	
TOTAL OF ABOVE CALCULATIONS =				$ 1,040.00	
Reduction for 1/2 for filing by small entity, if applicable (see below).			+	$	-
SUBTOTAL =				$ 1,040.00	
Processing fee of **$130.00 (156)** for furnishing the English translation later than 20 ☐ 30 ☐ months from the earliest claimed priority date (37 CFR 1.492(f)).			+	$	
TOTAL NATIONAL FEE =				$ 1,040.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00 (581)** per property			+	$	
TOTAL FEES ENCLOSED =				$ 1,040.00	
				Amount to be refunded:	$
				charged:	$

a. ☐ Small entity status is hereby claimed.

b. ☒ A check in the amount of $ 1,040.00 to cover the above fees is enclosed.

c. ☐ Please charge my Deposit Account No. 02-4800 in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

d. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-4800. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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SIGNATURE

Robert S. Swecker
NAME

19,885
REGISTRATION NUMBER

March 13, 2002
DATE

Patent
Attorney's Docket No. 027650-975

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	
	)	
HÅKAN MÖLLER, et al.	)	Group Art Unit: Unassigned
	)	
Application No.: Unassigned	)	Examiner: Unassigned
	)	
Filed: March 13, 2002	)	
	)	
For: A SYSTEM FOR MONITORING AND CONTROL IN THE STERILISATION OF AN OBJECT	)	

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination of the above-captioned patent application, it is requested that the claims of this application be amended as set forth herein. No new matter has been introduced in these amendments to the claims.

IN THE CLAIMS:

Please replace Claims 1-8 as follows.

1. (Amended) A system for monitoring and control in the sterilisation of an object which, for the purpose of sterilisation, is electron irradiated from an electron radiation source past which the object is led or conveyed in order to receive a sufficient irradiation dose for the intended sterilisation effect, wherein it includes:

A detector for sensing the current speed of the object at the electron radiation source and generating an electric output signal which corresponds to the sensed speed;

A speed/voltage converter which has an input in communication with the detector for receiving the output signal from the detector and generating a control signal proportional to a norm value for filament current to the electron radiation source as a response thereto;

A high voltage/filament current generator which has an input for receiving a set norm value signal and, for generating in response thereto a high voltage at a first output in communication with the electron radiation source, a filament current at a second output in communication with the electron radiation source, an output signal for pertinent high voltage at a third output, and an output signal for pertinent filament current at a fourth output;

A process control unit which has a first input in communication with the converter for receiving the control signal from the converter, a second input in communication with the third output at the generator for receiving the generated output signal for pertinent high voltage, a third input in communication with the fourth output at the generator for receiving the generated output signal for pertinent filament current, said process control unit being disposed to compare the received electric signals with corresponding norm values pre-programmed in the process control unit and generating a positive electric comparison signal when the received signals correspond to the pre-programmed norm values, and a negative comparison signal when the received signals deviate prohibitively from the pre-programmed norm values in the comparison;

An ejector mechanism at or downstream of the electron radiation source in communication with the process control unit, for receiving the generated comparison signal from the process control unit, said ejector mechanism being disposed to be activated for ejecting the sterilised objects when the received comparison signal is negative, and to be inactivated when the received comparison signal is positive.

2. (Amended) The system as claimed in Claim 1, wherein it also includes a logging unit which has a first input in communication with the converter for receiving and storing the norm value signal from the converter, a second input in communication with the third output at the generator for receiving and storing the output signal for pertinent high voltage and a third input in communication with the fourth output at the generator for receiving and storing the output signal for pertinent filament current.

3. (Amended) The system as claimed in Claim 1, wherein it has a dosimeter at the electron radiation source for continuous measurement of the relevant electron irradiation dose from the electron radiation source and for generating, in response to the relevant electron irradiation dose, an electric signal for transmission to the process control unit which has a fourth input in communication with the dosimeter.

4. (Amended) The system as claimed in Claim 3, wherein the dosimeter is also in communication with the logging unit which has a fourth input in communication with the dosimeter.

5. (Amended) The system as claimed in Claim 3, wherein the process control unit is disposed to generate a positive electric comparison signal when the received output signal from the dosimeter corresponds with a norm value pre-programmed in the process control unit for electron irradiation dose, and a negative comparison signal when the received output signal from the dosimeter deviates prohibitively from the pre-programmed norm value for electron irradiation dose.

6. (Amended) The system as claimed in Claim 3, wherein the dosimeter is disposed to transmit the output signal to the process control unit and the logging unit, respectively, via an amplifier.

7. (Amended) The system as claimed in Claim 1, wherein the object which is to be sterilised is a sheet- or web-shaped packaging blank for aseptic packages.

8. (Amended) The system as claimed in Claim 1, wherein the object which is to be sterilised is a ready-to-fill package.

REMARKS

By way of the foregoing amendments to the claims, Claims 1-8 have been amended to delete the multiple dependencies and the reference numerals, and to replace the words "characterised in that" with the word "wherein". These changes have been made in accordance with 37 C.F.R. § 1.121 as amended on November 7, 2000. Marked-up versions of Claims 1-8 indicating the changes accompany this Preliminary Amendment.

It is requested that the application be examined on the basis of the claims as amended.

Early and favorable consideration with respect to this application is respectfully requested.

Should any questions arise in connection with this application, the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____

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Date: March 13, 2002

Attachment to Preliminary Amendment dated March 13, 2002

Marked-up Claims 1-8

1. (Amended) A system for monitoring and control in the sterilisation of an object [(1; 1')] which, for the purpose of sterilisation, is electron irradiated from an electron radiation source [(2; 2')] past which the object [(1; 1')] is led or conveyed in order to receive a sufficient irradiation dose for the intended sterilisation effect, [characterised in that] wherein it includes:

A detector [(11; 11')] for sensing the current speed of the object [(1; 1')] at the electron radiation source [(2; 2')] and generating an electric output signal which corresponds to the sensed speed;

A speed/voltage converter [(13, 13')] which has an input in communication with the detector [(11; 11')] for receiving the output signal from the detector [(11; 11')] and generating a control signal proportional to a norm value for filament current to the electron radiation source [(2; 2')] as a response thereto;

A high voltage/filament current generator [(18; 18')] which has an input for receiving a set norm value signal and, for generating in response thereto a high voltage at a first output in communication with the electron radiation source [(2; 2')], a filament current at a second output in communication with the electron radiation source [(2; 2')], an output signal for pertinent high voltage at a third output, and an output signal for pertinent filament current at a fourth output;

A process control unit [(19; 19')] which has a first input in communication with the converter [(13; 13')] for receiving the control signal from the converter [(13; 13')], a second input in communication with the third output at the generator [(18; 18')] for receiving the

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Marked-up Claims 1-8

generated output signal for pertinent high voltage, a third input in communication with the fourth output at the generator [(18; 18')] for receiving the generated output signal for pertinent filament current, said process control unit [(19; 19')] being disposed to compare the received electric signals with corresponding norm values pre-programmed in the process control unit [(19; 19')] and generating a positive electric comparison signal when the received signals correspond to the pre-programmed norm values, and a negative comparison signal when the received signals deviate prohibitively from the pre-programmed norm values in the comparison;

An ejector mechanism [(26; 26')] at or downstream of the electron radiation source [(2; 2')] in communication with the process control unit [(19; 19')], for receiving the generated comparison signal from the process control unit [(19; 19')], said ejector mechanism [(26; 26')] being disposed to be activated for ejecting the sterilised objects [(1; 1')] when the received comparison signal is negative, and to be inactivated when the received comparison signal is positive.

2. (Amended) The system as claimed in Claim 1, [characterised in that] wherein it also includes a logging unit [(23; 23'')] which has a first input in communication with the converter [(13; 13')] for receiving and storing the norm value signal from the converter [(13; 13')], a second input in communication with the third output at the generator [(18; 18')] for receiving and storing the output signal for pertinent high voltage and a third input in

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Marked-up Claims 1-8

communication with the fourth output at the generator [(18; 18')] for receiving and storing the output signal for pertinent filament current.

3. (Amended) The system as claimed in Claim 1 [or 2], [characterised in that] wherein it has a dosimeter [(128)] at the electron radiation source [(2')] for continuous measurement of the relevant electron irradiation dose from the electron radiation source [(2')] and for generating, in response to the relevant electron irradiation dose, an electric signal for transmission to the process control unit [(19')] which has a fourth input in communication with the dosimeter [(128)].

4. (Amended) The system as claimed in Claim 3, [characterised in that] wherein the dosimeter [(128)] is also in communication with the logging unit [(23')] which has a fourth input in communication with the dosimeter [(128)].

5. (Amended) The system as claimed in Claim 3 [or 4], [characterised in that] wherein the process control unit [(19')] is disposed to generate a positive electric comparison signal when the received output signal from the dosimeter [(128)] corresponds with a norm value pre-programmed in the process control unit [(19')] for electron irradiation dose, and a negative comparison signal when the received output signal from the dosimeter [(128)] deviates prohibitively from the pre-programmed norm value for electron irradiation dose.

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Marked-up Claims 1-8

6. (Amended) The system as claimed in [any of Claims 3 to 5] Claim 3, [characterised in that] wherein the dosimeter [(128)] is disposed to transmit the output signal to the process control unit [(19')] and the logging unit [(23')], respectively, via an amplifier [(129)].

7. (Amended) The system as claimed in [any of the preceding Claims] Claim 1, [characterised in that] wherein the object [(1; 1')] which is to be sterilised is a sheet- or web-shaped packaging blank for aseptic packages [(3; 3')].

8. (Amended) The system as claimed in [any of Claims 1 to 7] Claim 1, [characterised in that] wherein the object [(1; 1')] which is to be sterilised is a ready-to-fill package.

A SYSTEM FOR MONITORING AND CONTROL IN THE STERILISATION OF AN OBJECT

TECHNICAL FIELD

The present invention relates to a system for monitoring and control in the sterilisation of an object which, for the purpose of sterilisation, is electron irradiated from an electron radiation source past which the object is led or conveyed in order to receive the requisite radiation dose for the desired sterilisation effect. In particular, the present invention relates to such a system for the sterilisation of a planar or optionally configured packaging blank.

BACKGROUND ART

Within the packaging technology, use is often made of consumer packages of single-use disposable type for packing and transporting liquid foods. The demands placed on such so-called single-use disposable packages is that they must be easy to produce and handle and that they, moreover, impart to their packed product the requisite product protection in order to be able to store the product in an unopened package without the risk that the product deteriorate and become unfit for consumption.

The requirement on requisite product protection is, of course, particularly important when the product which is to be packed is a food, and in order to make for reliable handling of a packed food, use is therefore most generally made of so-called aseptic packages which are a special type of the above-mentioned single-use packages. An aseptic package differs from a corresponding non-aseptic package principally in that the aseptic package, prior to filling, is subjected to a bactericidal treatment (e.g. a sterilisation treatment) and that the thus treated package is thereafter filled and sealed under sterile conditions in order to reduce the risk of re-infection.

Aseptic single-use packages are produced, for example, from a web of a packaging material in that the web is, for the purpose of sterilisation, led through a bath of aqueous hydrogen peroxide solution and thereafter reformed into packages which are filled with the pertinent, separately sterilised product and sealed in a sterile filling atmosphere. The entire production cycle, including the

sterilisation, is put into effect with the aid of modern, rational packaging and filling machines of the type which both form, fill and seal aseptic packages at a product output speed of several thousands of packages per hour, practically round the clock, without disruption other than for planned normal operational maintenance.

Since such high production output speeds require correspondingly extremely high web speeds, it is obvious that the contact of the web with the sterilising hydrogen peroxide bath will be only brief, unless the bath is extended to an excessive length. In order to achieve the desired sterilisation effect at these high production output speeds, it is therefore important that all parameters relevant for the sterilisation, e.g. temperature, concentration etc., are monitored and maintained at their predetermined levels throughout the entire production cycle in order to avoid unnecessary production waste because of insufficient sterilisation of the web.

In the described, prior art packaging production, the temperature and hydrogen peroxide concentration of the sterilisation bath are set initially at their respective levels for the desired sterilisation of the web at the current web speed, whereafter the temperature of the bath is continuously monitored during the sterilisation, while the concentration of the bath is only monitored at predetermined time intervals, e.g. after four or eight hours. Such an intermittent monitoring is unsatisfactory and can, in the worst case scenario, lead to all packages produced during the meantime having to be rejected (product waste) if it proves at the time of monitoring that the concentration drastically or prohibitively deviates from the predetermined concentration level.

Another drawback inherent in the prior art sterilisation method is that it requires careful and complete removal of hydrogen peroxide from the web after passage through the hydrogen peroxide bath in order to eliminate the risk that hydrogen peroxide accompanies the web and finally comes into contact with the product which is to be packed.

Efficient removal of hydrogen peroxide from the web is, as a rule, easy to achieve in such cases where the web is entirely smooth, but is more difficult if the web displays irregularities on its surface, e.g. applied opening strips etc., where the hydrogen peroxide may readily penetrate in and become

inaccessible. The problem with residual quantities of hydrogen peroxide in the sterilise web is further aggravated in those cases where the web displays incision edges with exposed paper or paperboard fibre which readily absorb and conceal residual quantities of hydrogen peroxide in the fibre layer of the web.

The problem in connection with hydrogen peroxide in a packaging material which, for the purpose of sterilisation, has been in contact with an aqueous hydrogen peroxide solution is wholly obviated by another prior art sterilisation method in which the packaging material, for the purpose of sterilisation, is irradiated with emitted electrons from an electron radiation source which directs electron beams at at least those parts of the packaging material which later come into contact with a product packed in the sterilised packaging material.

A sterilisation method which employs electron irradiation instead of hydrogen peroxide as the sterilisation agent is extremely rapid and efficient in the sterilisation of packaging material and/or ready-to-fill packages, but none of the hitherto prior art electron irradiation methods has a system for the continuous monitoring and control of the sterilisation throughout the entire sterilisation process. In particular, the prior art electron irradiation methods lack a system which is capable of responding instantaneously to a detected deviation in a monitored process parameter and immediately thereafter activating a control unit for correcting the deviating parameter back to the correct level, at the same time as only that part of the packaging material which had been sterilised at the incorrect parameter level is automatically rejected without needing to stop the sterilisation process.

OBJECTS OF THE INVENTION

One object of the present invention is therefore to obviate the above-considered shortcomings and drawbacks inherent in the above-described sterilisation methods.

A further object of the present invention is to provide an efficient and reliable system for monitoring and control in the sterilisation of an object which, for the purpose of sterilisation, is electron irradiated from an electron radiation

source past which the object is led or conveyed at a predetermined speed in order to receive a sufficient irradiation dose for the intended sterilisation effect.

A particular object of the present invention is to provide a system for monitoring and control in the sterilisation of a packaging material or a package by means of electron irradiation, which makes for continuous monitoring and control of the sterilisation process and the immediate rejection of incorrectly sterilised packaging material, without the sterilisation process or operation otherwise needing to be stopped.

SOLUTION

These objects will be attained according to the present invention by means of the system defined in appended Claim 1. Further advantageous details and aspects of the present invention are apparent from the appended subclaims.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

The present invention will now be described in greater detail hereinbelow, with particular reference to the accompanying Drawings. In the accompanying Drawings:

Fig. 1 is a schematic block diagram which shows a system for monitoring and control according to a first embodiment of the present invention in connection with the electron sterilisation of a packaging material web; and

Fig. 2 is a schematic block diagram which shows a system for monitoring and control according to a second embodiment of the present invention in the electron sterilisation of a packaging material web.

It should be observed that, while the description with reference to the accompanying Drawings particularly refers to the sterilisation of a packaging material web as example of an object which is to be electron sterilised, the present invention is not restricted exclusively to this particular application. The present invention may be employed in the sterilisation also of other types and forms of objects, such as, for example, individual sheet-shaped packaging blanks, open, ready-to-fill packages etc. The expression "object" as employed here and in the appended Claims is thus intended to encompass any type and form of object which is suitable for a continuous electron sterilisation.

DESCRIPTION OF PREFERRED EMBODIMENTS

Fig. 1 thus shows a simplified block diagram of a system according to a first embodiment of the present invention, carrying the generic reference numeral 10, in the sterilisation of a web 1 of a packaging material which, for the purpose of sterilisation, is irradiated with electrons from an electron radiation source 2 past which the web 1 is led or conveyed at a predetermined web speed in order, on its surface, to receive a sufficient electron dose for the desired sterilisation effect.

From the electron radiation source 2, the web 1 is led further to a forming and filling station (not shown) where the electron-sterilised web 1 is formed into packages which are filled with optional sterilised product and sealed to make finished packages 3 for further transport on a conveyor belt 4.

In the illustrated example, both the sterilisation of the web 1 and the forming, filling and sealing of the finished packages 3 take place with the aid of an aseptic packing and filling machine of the type which both sterilises, forms, fills and seals finished packages from a reel of the web-shaped packaging material magazined at the infeed end of the machine.

The system 10 for continuous monitoring and control of the electron sterilisation has a detector 11 placed at the electron radiation source 2 for sensing the pertinent web speed of the web 1 and in response the sensed web speed generating an electric signal which, via a conductor 12, is transmitted to a speed/voltage converter 13 which has an input in communication with the conductor 12.

The speed/voltage converter 13 converts the received electric signal into a process control signal which, in the current example, is a control signal calibrated with a norm value for filament current as the output signal. This output signal is transmitted via the conductor 14 and conductors 16 and 17 to a process control unit 19 which has a first input in communication with the conductor 17, and partly via the conductor 16 to a logging unit 23 which has a first input in communication with the conductor 16.

From a set norm value signal for filament current, the high voltage/filament current generator 18 generates an electric high voltage at a first output and an electric filament current at a second output, as well as an electric

output signal proportional to the high voltage level at a third output and an electric output signal proportional to the filament current level at a fourth output.

The electric high voltage is transmitted via an electric cable 20a to the electron radiation source 2 which has a first input in communication with the cable 20a, and the electric filament current is transmitted via an electric cable 20b to the electron radiation source 2 which has a second input in communication with the cable 20b. Between the generator 18 and the electron radiation source 2, there is also disposed a zero conductor 20c.

The electric output signal for pertinent high voltage level is transmitted, on the one hand, via conductors 21 and 22 to the process control unit 19 which has a second input in communication with the conductor 22, and, on the other hand, via the conductor 21 to the logging unit 23 which has a second input in communication with the conductor 21.

The electric output signal for pertinent filament current is transmitted, on the one hand, via conductors 24 and 25 to the process control unit 19 which has a third input in communication with the conductor 25, and, on the other hand, via the conductor 24 to the logging unit 23 which has a third input in communication with the conductor 24.

On receipt of the output signals from the high voltage/filament current generator 18, the process control unit 19 compares these with corresponding, already input programmed norm values and generates, from these comparisons, either a positive electric comparison signal when these correspond to the predetermined norm values, or a negative electric comparison signal when the received signals from the high voltage/filament current generator 18 deviate prohibitively from the predetermined norm values.

The generated electric comparison signals are transmitted via a conductor 27 to an actuable ejector mechanism 26 with an ejector arm 26a at the discharge end of the packing and filling machine.

On receipt of a negative electric comparison signal, the ejector mechanism 26 activates the reciprocating ejector arm 26a for ejecting a discharged package 3, and on receipt of a positive electric comparison signal, the ejector mechanism 26 remains inactive and the ejector arm 26a thereby remains

stationary so that discharged packages 3 may pass the ejector arm 26a unimpeded and be collected on the conveyor belt 4 for further transport and handling.

In the example above, it is assumed that the aseptic packing and filling machine is set to produce approximately 7,000 aseptic packages per hour, which corresponds to a web speed of approximately 0.6 m/s. It is further assumed that the electron radiation source 2 has a window directed towards the web 1 and that the distance between the web 1 and the window is set at approximately 12 mm.

On these assumptions, it is known that a satisfactory sterilisation effect will be obtained if the electron irradiation dose received by the web 1 on passage past the window of the electron radiation source 2 may be between 5 and 50 kGy, typically 25 kGy, and under the given assumptions, this dose will be achieved as long as the electron radiation source is supplied with a high voltage level between 40 and 90 kV, e.g. 75 kV, and a filament current level at. for example, 2.5 A depending upon the desired electron radiation dose. Should, for some reason, the high voltage level and/or the filament current level temporarily or permanently fall to values below these levels, the received electron radiation dose will be less and can be lower than 25 kGy, with the result that the web 1 will be insufficiently sterilised and that the produced packages will consequently be unusable.

If the speed of the web 1 were, for some reason, to be reduced and be lower than the set web speed, this entails (on condition that the remaining parameters are maintained according to the assumption above) that the web will receive an unnecessarily large electron radiation dose, with excessive sterilisation as a consequence. Should, on the other hand, the speed of the web 1 temporarily increase and be greater than the set web speed, the web will receive far too slight an electron irradiation dose and will be insufficiently sterilised, with unusable packages as a result, as long as the electron irradiation dose of the web is less than 25 kGy.

With the system in Fig. 2, the sterilisation process in Fig. 1 is monitored and controlled in such a manner that the electron irradiation dose received by the web 1 is constantly maintained at at least 25 kGy, at the same time as packages 3 are immediately ejected by means of the ejector mechanism 26 if the electron irradiation dose were, for some reason, to fall below 25 kGy.

As was described previously, the detector 11 continuously senses the speed of the web 1 at the electron radiation source 2 and generates, in response to the sensed speed, an output signal which is transmitted to the speed/voltage converter 13. The speed/voltage converter 13 receives the signal and converts it into an electric norm value signal for filament current which is transmitted, on the one hand, to the high voltage/filament current generator 18 and, on the other hand, to the process control unit 19. If the received, set norm value signal at the high voltage/filament current generator 18 is lower than the filament current signal which, on the occasion of sensing by the detector, is transmitted to the electron radiation source, the high voltage/filament current generator 18 generates, at its second output, an electric filament current signal for reducing the pertinent filament current to the electron radiation source for the immediate adjustment of the filament current to the correct level in view of the sensed web speed. At the same time, the process control unit 19 generates a negative electric output signal which is immediately transmitted to and activates the ejector mechanism 26 for ejecting the package(s) sterilised at the sensed, incorrect web speed.

If the set norm value signal at the high voltage/filament current generator 18 is higher than the filament current signal which, on the occasion of sensing by the detector, is transmitted to the electron radiation source, the high voltage/filament current generator 18 generates, at its second output, an electric filament current signal for increasing the pertinent filament current to the electron radiation source for the immediate adjustment of the filament current to the correct, higher level in view of the sensed web speed. At the same time, the process control unit 19 generates a negative electric output signal for transmission to and activation of the ejector mechanism 26, as previously.

If the set norm value signal at the high voltage/filament current generator 18 corresponds to the filament current signal which, on the occasion of sensing by the detector, is transmitted to the electron radiation source, the high voltage/filament current generator continues to transmit the same filament current signal to the electron radiation source as before. At this norm value signal, the process control unit 19 generates a positive electric output signal for transmission to the ejector mechanism 26 which, thus is not activated, but allows the packages to freely pass the ejector arm 26a.

All relevant real time parameter signals for monitoring and control of the sterilisation process are registered and stored continuously in the logging unit 23 throughout the entire sterilisation cycle.

In the illustrated system in Fig. 1, the process control unit 19 may preferably also be pre-programmed to generate a stop signal for stopping the web 1 and discontinuing the process entirely in such cases where, for example, the generator 18 twice or more in succession generates correction signals for filament current and/or high voltage to the electron radiation source 2. This may occur, for example, when the relevant high voltage level, because of operational disruptions in the outer mains power supply suddenly, but not just briefly, falls below a predetermined minimum level or to zero.

Fig. 2 shows a schematic block diagram of a system according to a second embodiment of the present invention which differs from the illustrated system in Fig. 1 principally in that it also includes one or more detectors (not shown) disposed at the electron radiation source 2 in communication with an amplifier 129 for detecting the electron irradiation dose emitted from the electron radiation source. Since the system in Fig. 2 otherwise includes substantially the same components as the system according to the first embodiment, the same or similar components have been given the same reference numerals as in Fig. 1 for purposes of clarity, but with the addition of a prima (') symbol.

The amplifier 129 receives and amplifies an electric output signal generated by the detector or the electron dosimeter 128 in response to the detected electron dose and generates an output signal which is transmitted, on the one hand, via conductors 131 and 132 to the process control unit 19' which has a fourth input in communication with the conductor 132 and, on the other hand, to the logging unit 23' which has a fourth input in communication with the conductor 131.

On the same assumptions in the description above of the system in Fig. 1 concerning the set web speed (e.g. 0.6 m/s) and distance (e.g. 12 mm) between the electron radiation source 2' and the web 1', it will be assumed also in this case that sufficient sterilisation effect is obtained at an electron irradiation dose of at least 25 kGy corresponding to a high voltage level of 75 kV and a filament current level of 2.5 A for the electron radiation source 2'.

If the speed of the web 1' should, for some reason, increase and be higher than the assumed web speed, i.e. 0.6 m/S, this entails that the web 1' receives a far too slight electron irradiation dose and consequently will be insufficiently sterilised as long as the received electron irradiation dose of the web is less than 25 kGy.

With the system in Fig. 2, the sterilisation process is monitored and controlled in the same manner as in the example in Fig. 1 in such a manner that the received electron irradiation dose throughout the entire sterilisation process is maintained at at least 25 kGy, at the same time as packages 3' are immediately ejected by means of the ejector mechanism 26' if the electron irradiation dose were, for some reason, to fall below 25 kGy.

As was described earlier, the detector 11' continuously senses the speed of the web 1' at the electron radiation source 2' and generates, in response to the sensed speed, an output signal which is transmitted to the speed/voltage converter 13'. The speed/voltage converter 13' receives the signal and converts it into an electric norm value signal for filament current which is transmitted, on the one hand, to the high voltage/filament current generator 18' and, on the other hand, to the process control unit 19'.

If the set norm value signal at the high voltage/filament current generator 18' is lower than the filament current signal which, on the occasion of sensing by the detector, is transmitted to the electron radiation source, the high voltage/filament current generator 18' generates, at its second output, an electric filament current signal for reducing the pertinent filament current to the electron radiation source for the immediate adjustment of the filament current to the correct level in view of the sensed web speed. At the same time, the process control unit 19' generates a negative electric output signal which is immediately transmitted to and activates the ejector mechanism 26' for ejecting the package(s) sterilised at the sensed, incorrect web speed.

If the set norm value signal at the high voltage/filament current generator 18' is higher than the filament current signal which, on the occasion of sensing by the detector, is transmitted to the electron radiation source, the high voltage/filament current generator 18' generates, at its second output, an electric filament current signal for increasing the pertinent filament current to the electron

radiation source for the immediate adjustment of the filament current to the correct, higher level in view of the sensed web speed. At the same time, the process control unit 19' generates a negative electric output signal for transmission to and activation of the ejector mechanism 26', as previously.

If the set norm value signal at the high voltage/filament current generator 18' corresponds to the filament current signal which, on the occasion of sensing by the detector, is transmitted to the electron radiation source, the high voltage/filament current generator continues to transmit the same filament current signal to the electron radiation source as before. At this norm value signal, the process control unit 19' generates a positive electric output signal for transmission to the ejector mechanism 26' which, thus is not activated, but allows the packages 3' to freely pass the ejector arm 26'a.

With the aid of the detector or the electron irradiation dosimeter 128, the system in Fig. 2 can, unlike the system in Fig. 1, also monitor and control the process by detecting and output parameter, i.e. the electron irradiation dose from the electron radiation source 2' and thus not only by detecting an input parameter, such as web speed, which further increases the reliability of the system in continuous monitoring and control of the sterilisation. Should, in this example, the instantaneously detected electron irradiation dose fall below the predetermined requisite value, i.e. 25 kGy, the process control unit 19' will, on receipt of the output signal from the amplifier 129, immediately activate the ejector mechanism 26' for ejecting packages 3' which have been insufficiently sterilised because of the far too low electron irradiation dose at the relevant occasion of detection.

Thus, it will be apparent from the foregoing description that the present invention provides a system for monitoring and control which effectively and simply obviates the previously considered shortcomings and drawbacks in connection with the conventional sterilisation methods. In particular, the present invention realises a system by means of which electron sterilisation of a sheet- or web-shaped, or otherwise configured packaging blank may be continuously monitored and controlled throughout the entire sterilisation process in such a manner that an incorrectly sterilised packaging blank, or packages produced from the incorrectly sterilised packaging blank, may be immediately ejected without the sterilisation process needing to be discontinued as a result of the incorrect

sterilisation. It will be obvious to a person skilled in the art that alterations and modifications in the two described embodiments may be put into effect without departing from the inventive concept as this is defined by means of the appended Claims. Thus, the appended Claims are intended also to encompass such alterations and modifications as are obvious to a person skilled in the art.

WHAT IS CLAIMED IS:

1. A system for monitoring and control in the sterilisation of an object (1; 1') which, for the purpose of sterilisation, is electron irradiated from an electron radiation source (2; 2') past which the object (1; 1') is led or conveyed in order to receive a sufficient irradiation dose for the intended sterilisation effect, **characterised in that** it includes:

A detector (11; 11') for sensing the current speed of the object (1; 1') at the electron radiation source (2; 2') and generating an electric output signal which corresponds to the sensed speed;

A speed/voltage converter (13; 13') which has an input in communication with the detector (11: 11') for receiving the output signal from the detector (11; 11') and generating a control signal proportional to a norm value for filament current to the electron radiation source (2; 2') as a response thereto;

A high voltage/filament current generator (18; 18') which has an input for receiving a set norm value signal and, for generating in response thereto a high voltage at a first output in communication with the electron radiation source (2; 2'), a filament current at a second output in communication with the electron radiation source (2; 2'), an output signal for pertinent high voltage at a third output, and an output signal for pertinent filament current at a fourth output;

A process control unit (19; 19') which has a first input in communication with the converter (13; 13') for receiving the control signal from the converter (13; 13'), a second input in communication with the third output at the generator (18; 18') for receiving the generated output signal for pertinent high voltage, a third input in communication with the fourth output at the generator (18; 18') for receiving the generated output signal for pertinent filament current, said process control unit (19; 19') being disposed to compare the received electric signals with corresponding norm values pre-programmed in the process control unit (19; 19') and generating a positive electric comparison signal when the received signals correspond to the pre-programmed norm values, and a negative comparison signal when the received signals deviate prohibitively from the pre-programmed norm values in the comparison;

An ejector mechanism (26; 26') at or downstream of the electron radiation source (2; 2') in communication with the process control unit (19; 19'), for receiving the generated comparison signal from the process control unit (19; 19'), said ejector mechanism (26; 26') being disposed to be activated for ejecting the sterilised objects (1; 1') when the received comparison signal is negative, and to be inactivated when the received comparison signal is positive.

2. The system as claimed in Claim 1, **characterised in that** it also includes a logging unit (23; 23') which has a first input in communication with the converter (13; 13') for receiving and storing the norm value signal from the converter (13; 13'), a second input in communication with the third output at the generator (18; 18') for receiving and storing the output signal for pertinent high voltage and a third input in communication with the fourth output at the generator (18; 18') for receiving and storing the output signal for pertinent filament current.

3. The system as claimed in Claim 1 or 2, **characterised in that** it has a dosimeter (128) at the electron radiation source (2') for continuous measurement of the relevant electron irradiation dose from the electron radiation source (2') and for generating, in response to the relevant electron irradiation dose, an electric signal for transmission to the process control unit (19') which has a fourth input in communication with the dosimeter (128).

4. The system as claimed in Claim 3, **characterised in that** the dosimeter (128) is also in communication with the logging unit (23') which has a fourth input in communication with the dosimeter (128).

5. The system as claimed in Claim 3 or 4, **characterised in that** the process control unit (19') is disposed to generate a positive electric comparison signal when the received output signal from the dosimeter (128) corresponds with a norm value pre-programmed in the process control unit (19') for electron irradiation dose, and a negative comparison signal when the received output signal from the dosimeter (128) deviates prohibitively from the pre-programmed norm value for electron irradiation dose.

6. The system as claimed in any of Claims 3 to 5, **characterised in that** the dosimeter (128) is disposed to transmit the output signal to the process control unit (19') and the logging unit (23'), respectively, via an amplifier (129).

7. The system as claimed in any of the preceding Claims, **characterised in that** the object (1; 1') which is to be sterilised is a sheet- or web-shaped packaging blank for aseptic packages (3; 3').

8. The system as claimed in any of Claims 1 to 7, **characterised in that** the object (1; 1') which is to be sterilised is a ready-to-fill package.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 March 2001 (22.03.2001)

PCT

(10) International Publication Number
WO 01/19687 A1

(51) International Patent Classification[7]: B65B 55/08, A61L 2/08

(21) International Application Number: PCT/SE00/01782

(22) International Filing Date:
14 September 2000 (14.09.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
9903332-6 17 September 1999 (17.09.1999) SE

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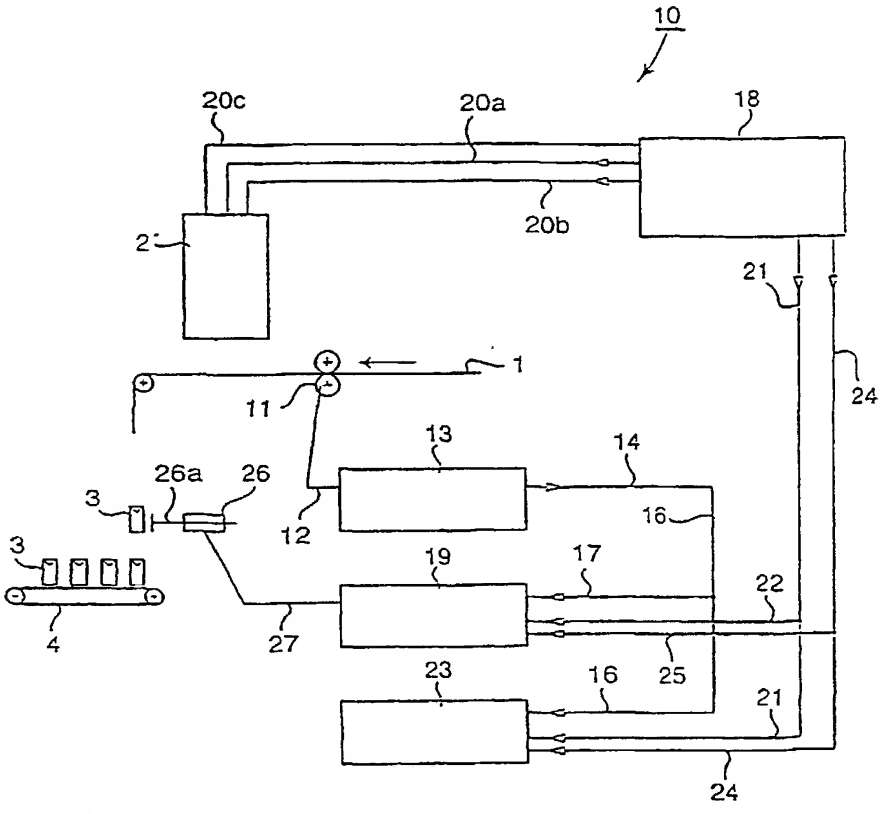
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,

[Continued on next page]

(54) Title: A SYSTEM FOR MONITORING AND CONTROL IN THE STERILISATION OF AN OBJECT



(57) Abstract: The disclosure relates to a system for monitoring and control in the sterilisation of an object (1) which, for the purpose of sterilisation, is electron irradiated from an electron radiation source (2) past which the object is led or conveyed. The system includes a detector (11), a converter (13), a generator (18), a process control unit (19), as well as an ejector mechanism (26) which is disposed to be activated for ejecting the sterilised object (1) on receipt of a negative comparison signal from the process control unit (19).

WO 01/19687 A1

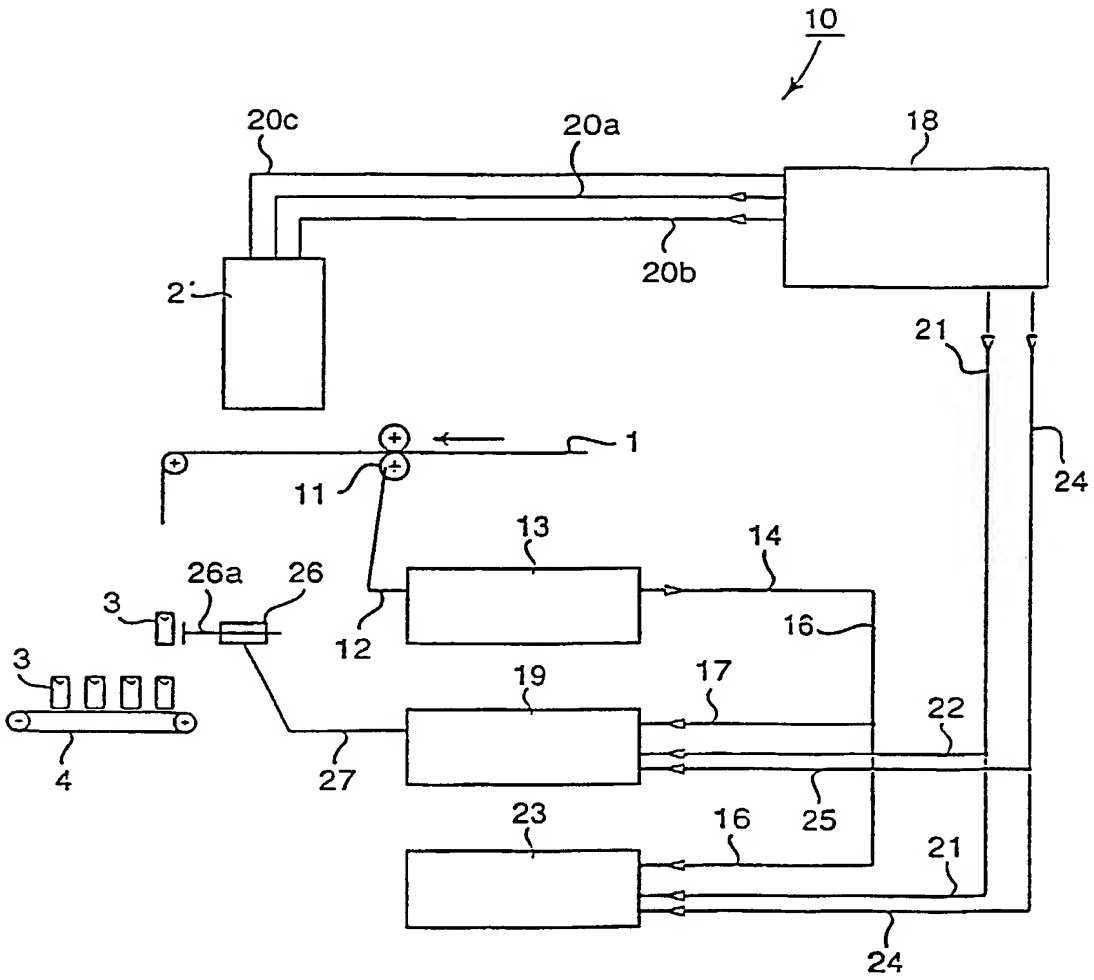

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Fig 1

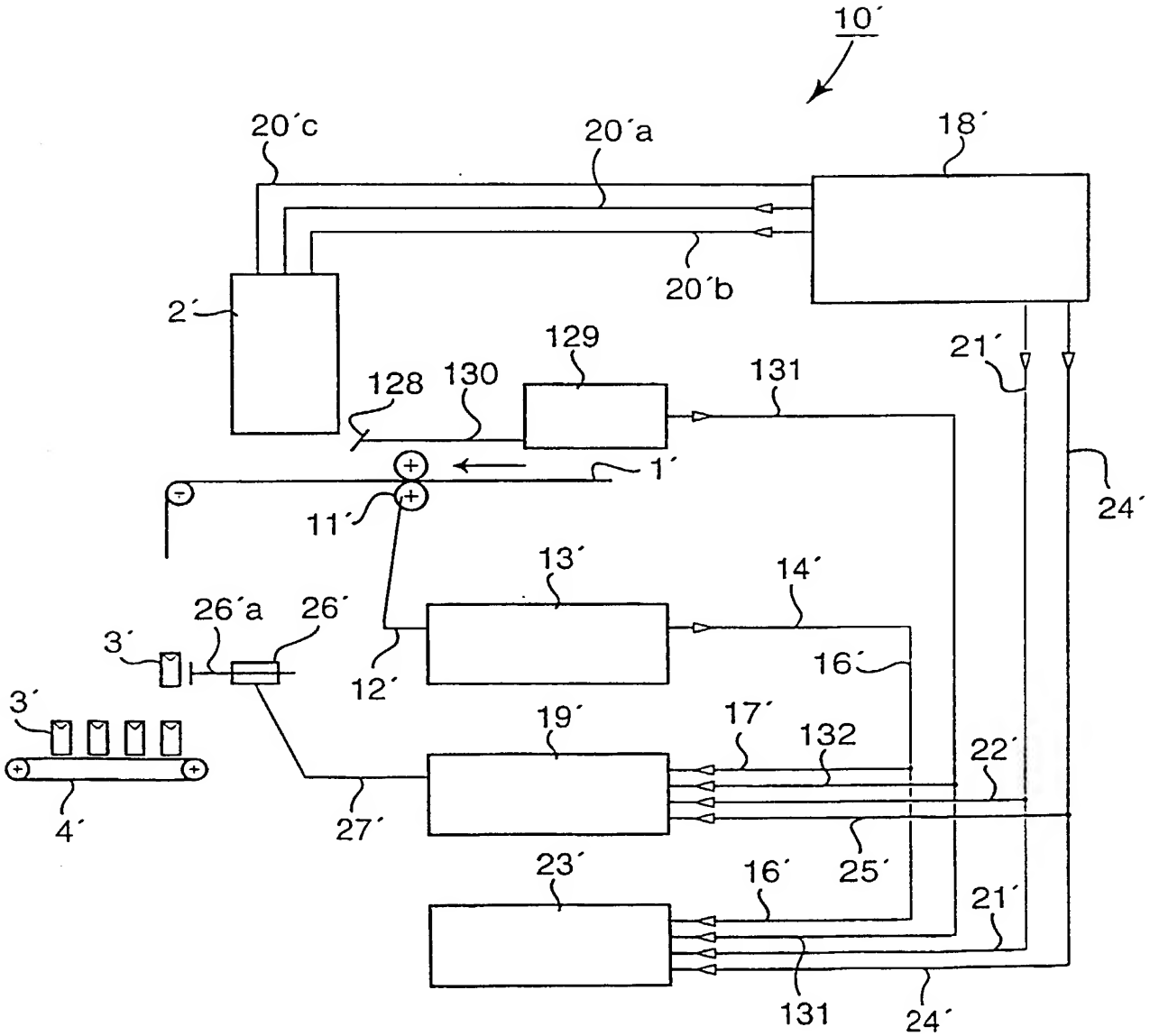
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Fig 2

10070926 .072002

TP 1332-US

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to Provisional and International (PCT) Applications)	Attorney's Docket No.

As a below named inventor, I hereby declare that:
My residence, post office address and citizenship are as stated below next to my name;
I BELIEVE I AM THE ORIGINAL, FIRST AND SOLE INVENTOR (IF ONLY ONE NAME IS LISTED BELOW) OR AN ORIGINAL, FIRST AND JOINT INVENTOR (IF PLURAL NAMES ARE LISTED BELOW) OF THE SUBJECT MATTER WHICH IS CLAIMED AND FOR WHICH A PATENT IS SOUGHT ON THE INVENTION ENTITLED:

——A SYSTEM FOR MONITORING AND CONTROL IN THE STERILISATION OF AN OBJECTX

The specification of which (check only one item below):

☐ is attached hereto.

☐ was filed as United States Patent Application Number _____
on _____
and was amended on _____ (if applicable).

X☐ was filed as International (PCT) Application Number ——PCT/SE00/01782
on 14 September 2000 (14.09.00)
and was amended on _____ (if applicable).

I HAVE REVIEWED AND UNDERSTAND THE CONTENTS OF THE ABOVE-IDENTIFIED SPECIFICATION, INCLUDING THE CLAIMS, AS AMENDED BY ANY AMENDMENT REFERRED TO ABOVE.

I ACKNOWLEDGE THE DUTY TO DISCLOSE TO THE U.S. PATENT AND TRADEMARK OFFICE ALL INFORMATION KNOWN TO ME TO BE MATERIAL TO PATENTABILITY AS DEFINED IN TITLE 37, CODE OF FEDERAL REGULATIONS, Sec. 1.56 (as amended effective March 16, 1992);

I do not know and do not believe the said invention was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to said application; that said invention was not in public use or on sale in the United States of America more than one year prior to said application; that said invention has not been patented or made the subject of an inventor's certificate issued before the date of said application in any country foreign to the United States of America on any application filed by me or my legal representatives or assigns more than six months prior to said application;

I hereby claim foreign priority benefits under Title 35, United States Code, §§ 119 (a)-(e) of any foreign application(s) for patent or inventor's certificate or of any International (PCT) Application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT International (PCT) Application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. §119:

COUNTRY (if PCT, indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 U.S.C §119
——Sweden	——9903332-6	——17 September, 2000 (00-09-17)	X☐Yes ☐No
			☐Yes ☐No
			☐Yes ☐No
			☐Yes ☐No
			☐Yes ☐No

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below.

_____ _____
(APPLICATION NUMBER) (FILING DATE)

_____ _____
(APPLICATION NUMBER) (FILING DATE)

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (CONT'D) (Includes Reference to Provisional and International (PCT) Applications)	Attorney's Docket No.

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States applications(s) or International (PCT) Application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to the patentability as defined in Title 37, Code of Federal Regulations § 1.56, which became available between the filing date of the prior application(s) and the national or international filing date of this application:

PRIOR U.S. APPLICATIONS OR INTERNATIONAL (PCT) APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. § 120:

U.S. APPLICATIONS		STATUS (check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
		☐	☐	☐

PCT APPLICATIONS DESIGNATING THE U.S.					
PCT APPLICATION NO.	PCT FILING DATE	U.S. APPLICATION NUMBERS ASSIGNED (if any)			
PCT/SE00/01782	14-09-00	Unassigned		X	

I hereby appoint the following attorneys and agent(s) to prosecute said application and to transact all business in the U.S. Patent and Trademark Office connected therewith and to file, prosecute and to transact all business in connection with international applications directed to said invention:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (CONT'D) (Includes Reference to Provisional and International (PCT) Applications)	Attorney's Docket No.

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FULL NAME OF FIFTH JOINT INVENTOR, IF ANY	SIGNATURE	DATE
RESIDENCE (CITY & STATE/COUNTRY)		CITIZENSHIP
POST OFFICE ADDRESS (HOME ADDRESS		
FULL NAME OF SIXTH JOINT INVENTOR, IF ANY	SIGNATURE	DATE
RESIDENCE (CITY & STATE/COUNTRY)		CITIZENSHIP
POST OFFICE ADDRESS (HOME ADDRESS		
FULL NAME OF SEVENTH JOINT INVENTOR, IF ANY	SIGNATURE	DATE
RESIDENCE (CITY & STATE/COUNTRY)		CITIZENSHIP
POST OFFICE ADDRESS (HOME ADDRESS		
FULL NAME OF EIGHTH JOINT INVENTOR, IF ANY	SIGNATURE	DATE
RESIDENCE (CITY & STATE/COUNTRY)		CITIZENSHIP
POST OFFICE ADDRESS (HOME ADDRESS		
FULL NAME OF NINTH JOINT INVENTOR, IF ANY	SIGNATURE	DATE
RESIDENCE (CITY & STATE/COUNTRY)		CITIZENSHIP
POST OFFICE ADDRESS (HOME ADDRESS)		
FULL NAME OF TENTH JOINT INVENTOR, IF ANY	SIGNATURE	DATE
RESIDENCE (CITY & STATE/COUNTRY)		CITIZENSHIP
POST OFFICE ADDRESS (HOME ADDRESS		